Change in correspondence address.

Applicants note that a Revocation and Substitute Power of Attorney incorporating a change in correspondence address is filed herewith. In accordance with the instructions provided therein, **please direct all future correspondence regarding the subject application to CUSTOMER NUMBER 22798, that is:**

22798

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35 U.S.C. §112.

Applicants note that rejections of various claims were made in paragraphs 7 through 17 of the 3/27/01 Office Action, yet the statutory basis for these rejections was not identified. For the purpose of this response, Applicants assume the rejections of these paragraphs were made under 35 U.S.C. §112, second paragraph. Should the Examiner wish to maintain these rejections in future Office Actions, Applicants request that the statutory basis of the rejection be identified.

Formal matters.

Claims 38 and 51 were rejected because of the recitation of a double colon "::" in claim 38 and re recitation of "and" in claim 51, line 2. These claims are amended herein thereby obviating this rejection.

Claims 10 and 40 were rejected as allegedly containing an improper Markush Group. Applicants note that claim 40 is not pending in the application. Claim 10 is amended herein to obviate this rejection.

35 U.S.C. §112

Claims 1-8 and 47-62 were rejected because it allegedly cannot be determined what sample is being tested, what sample is the control, and from which sample/correlations the various correlations are determined. Applicants traverse by argument and amendment.

Independent claims 1 and 47 are amended herein to clarify that the sample being tested is a sample comprising YKL-40, and that the control is the same sample derived from a normal healthy

human (claim 1) or mammal (claim 47). Accordingly, there is no ambiguity regarding which sample is being tested or from which sample the various correlations are determined. Accordingly, this rejection should be withdrawn.

Claims 1-18 were rejected as allegedly incomplete for omitting essential steps. In particular the Examiner alleged that the method steps should include a contacting step in which the reaction of the sample with the reagents necessary is recited and a detection step. Applicants respectfully traverse.

The Examiner is reminded that it is well established law that **an enablement rejection must be directed to the patentable or inventive principles of the claimed method.** *See, e.g., Application of Herschler*, 200 USPQ 711 (CCPA 1979) or *In re Fuetterer*, 265 USPQ 217 (C.C.P.A. 1963). In the instant case, **the present invention pertains to the discovery that elevated YKL-40 levels are indicative of the presence of a cancer or prognostic for the outcome of a cancer, not to particular methods of assaying YKL-40.** Indeed, the invention can be practiced with any convenient method of measuring YKL-40. The claims are commensurate to the scope of Applicants discovery. No essential step is omitted.

The situation is analogous to that described in *Application of Fuetterer*, 138 USPQ 217 (CCPA 1963). In *Fuetterer,* the applicant invented a novel rubber stock composition that included "an inorganic salt capable" of acting as a colloid suspending agent. The Examiner argued that the amount of experimentation required to successfully use undisclosed inorganic salts should require the applicant to restrict his claims to specific salts disclosed. The CCPA reversed the Examiner's rejection, explaining that the invention was not the salt, but the combination of inorganic salts with the other elements of the claim. The fact that nondisclosed inorganic salts might be later discovered did not preclude broad claims to the **inventive combination**.

Fuetterer was followed by *Application of Herschler*, 200 USPQ 711 (CCPA 1979). In *Herschler*, the applicant had discovered that DMSO was useful as a transdermal carrier for physiologically active steroids. The CCPA found that a priority application describing the use of DMSO to transport a particular steroid supported a claim to a method of transporting the genus of all steroids. Citing *Fuetterer*, the court explained that Herschler's claims were drawn to a method of administration of steroids and not to administration of a particular steroid compound. The court noted that **the inventive principle was directed to the method, and that the exemplification using specific steroids was not the point of patentability**.

In ***Fuetterer***, the invention was the combination of salts with other compounds; thus the teaching of *particular* salts was not the invention and was not the issue in enablement. Similarly, in ***Herschler*** the invention was a method of transporting steroids; the teaching of particular steroids was not the invention and was not the focus of enablement. Analogously, in the present case the invention is the recognition that elevated YKL-40 is indicative of the presence of a cancer or of a poor prognosis in a patient that has a cancer not a particular method of measuring YKL-40. Methods of detecting YKL-40 are known. Thus it is sufficient that the claims simply recite "measuring the level of YKL-40" and not recite a particular YKL-40 assay.

Moreover, to confine Applicants to a particular method of measuring YKL-40 effectively denies Applicants the benefit of their invention. Limiting the protection for Applicants' invention to the specific method of measuring YKL-40 renders the invention easy to "design around" as a competitor seeking to avoid infringement would merely have to use a different YKL-40 assay. Such a limitation is improper. As stated by the CCPA:

> To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts. *In re Goffe*, 191 USPQ 429, 431 (CCPA 1976).

As in *Goffe* where the court held that applicants were not to be limited to the single "agglomerable material" disclosed when other suitable materials could be determined without undue experimentation, here Applicants should not be limited to a particular method of measuring YKL-40, when other methods are known and/or may be identified without undue experimentation. For these reasons, Applicants submit that the rejection under 35 U.S.C. §112 is improper and should be withdrawn.

35 U.S.C. §112, second paragraph.

Claim 11 (Office Action paragraphs 11 and 12).

Claim 11 was rejected as allegedly unclear in the recitation of "level" and "Immunohistochemical staining". In particular, the Examiner alleged that "[I]t is not clear how Immunohistochemical staining can be used in a quantitative method to determine 'levels'". Applicants respectfully traverse.

The use of immunohistochemistry in a quantitative method to determine levels is well known to those of skill in the art. Such methods are described, for example, in *Quantitative Immunohistochemistry : Theoretical Background and Its Application in Biology and Surgical Pathology* Progress in Histochemistry and Cyto 24(3) Peter Fritz, H, Multhaupt, J. Hoenes, D. Lutz, R. Doerrer, eds. (1992).

A brief Medline search (of references prior to the priority date of the present application) yields literally hundreds of references teaching quantitative immunohistochemistry. A few examples include:

1. Zaidi *et al.* (1996) Quantitative immunohistochemical estimates of O6-alkylguanine-DNA alkyltransferase expression in normal and malignant human colon. *Clin Cancer Res* 2(3): 577-584;

2. Makkink *et al.* (1995) Quantitative immunohistochemistry using the CAS 200/486 image analysis system in invasive breast carcinoma: a reproducibility study. *Anal Cell Pathol* 8(3) 227-245;

3. Pappot *et al.* (1997) Levels of plasminogen activator inhibitor type 1 and urokinase plasminogen activator receptor in non-small cell lung cancer as measured by quantitative ELISA and semiquantitative immunohistochemistry. Lung Cancer 1997 17: 197-209

4. Thomas et al. (1997) A novel quantitative immunoassay system for p53 using antibodies selected for optimum designation of p53 status. J Clin Pathol 50: 143-147

5. Toyokuni et al. (1997) Quantitative immunohistochemical determination of 8-hydroxy-2'-deoxyguanosine by a monoclonal antibody N45.1: its application to ferric nitrilotriacetate-induced renal carcinogenesis model. 76: 365-374

6. Reeves et al. (1996) Quantitative radioimmunohistochemical measurements of p185(erbB-2) in frozen tissue sections. *J Histochem Cytochem* 44: 1251-1259

The Examiner is simply incorrect in her assertion that "[I]t is not clear how Immunohistochemical staining can be used in a quantitative method to determine 'levels'". Accordingly the rejection of claim 11 on these grounds should be withdrawn.

Claim 11 was also rejected because it "cannot be determined how cells comprise a biological sample". Applicants respectfully traverse.

The Cambridge International Dictionary of English (online at http://dictionary.cambridge.org/) defines the term comprise (a verb) as meaning:

> [T]o have as parts or members, **or to be (those parts or members)** [emphasis added]

Cells "comprise" a biological sample by being parts or members of that sample. The term is used consistently with standard English and in accordance with common patent usage. Accordingly the Examiner's rejection on these grounds is improper and should be withdrawn.

Claim 38 (Office Action, paragraph 13).

Claim 38 was rejected as allegedly unclear in the recitation of a "possible recurrence" of a cancer. The Examiner asserted that the metes and bounds of a possible recurrence cannot be determined. Applicants traverse.

The Examiner is reminded that a claim is definite if:

> [R]ead in light of the specification [it] reasonably **apprise**[s] those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits. [emphasis added] *Hybritech Inc. v Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1385, 231 USPQ 81 (Fed. Cir. 1986) cert. denied 480 U.S. 947 (1987).

In the instant case, the term "possible recurrence" is well understood by those of ordinary skill in the art. As indicated in the specification, the claimed methods are of particular use in the context of a differential diagnosis (*see, e.g.,* page 12, lines 18-21). In such a context, any one diagnostic metric (*e.g.* YKL-40 level) simply indicates the possible existence of the pathology (*e.g.* recurrence of cancer). It is the combination of diagnostic elements, of which YKL-40 level is but one, that provides a definitive diagnosis.

Thus the term "possible recurrence" would be recognized by one of ordinary skill in the art and interpreted according to it plain meaning, *i.e.,* that the elevated YKL-40 level would be an indicia of the possible recurrence of the cancer.

The phrase thus reasonably apprises one of skill in the art of the utilization and scope of the invention and is as precise as the subject matter permits. Accordingly the rejection of claim 38 on these grounds should be withdrawn.

Claim 39 (Office Action, paragraph 14).

Claim 39 was rejected as allegedly unclear in the recitation of a "multiplicity of instances". In particular, the Examiner alleged that it is not clear what would be considered a "multiplicity" and what would not. Applicants traverse.

The term "multiplicity" is a term of art commonly used in patents. The term "multiplicity" is typically understood to mean more than one (*i.e.* a plurality). In the present case, the phrase "a multiplicity of instances" is understood to mean "more than one instance." Accordingly, the term is not indefinite and the rejection of claim 39 on these grounds should be withdrawn.

Claim 47 (Office Action, paragraph 15).

Claim 47 was rejected as allegedly indefinite in the recitation of a "statistically significant difference". In particular, the Examiner alleged that it is not clear what "index

The term "statistically significant difference" is a term of art understood by those of skill to refer to a difference greater than that attributable to chance as evaluated by a method appropriate to the data set at hand. Numerous suitable statistical tests are known to those of skill in the art (*e.g.* t-test, analysis of variance (ANOVA), semiparametric techniques, non-parametric techniques (*e.g.* Wilcoxon Mann-Whitney Test, Wilcoxon Signed Ranks Test, Sign Test, Kruskal-Wallis Test, *etc.*).

The claim is generic with respect to the specific statistical test and only requires that a statistical test indicate a statistically significant difference. The phrase thus reasonably apprises one of skill in the art of the utilization and scope of the invention and is as precise as the subject matter permits. Accordingly the rejection of claim 47 on these grounds should be withdrawn.

Claim 48 (Office Action, paragraph 16).

Claim 48 was rejected as allegedly unclear in the recitation of "a tissue affected by cancer." Claim 48 is canceled with entry of this amendment thereby obviating this rejection.

Claim 49 (Office Action, paragraph 17).

Claim 49 rejected as allegedly unclear in the recitation of "whole blood". In particular, the Examiner alleged that it was note clear if the assay is to be conducted on whole blood or if the blood is to be clotted and the serum is to be tested. Applicants traverse.

The term "whole blood" as recited in claim 49 pertains to the sample that is obtained. One of skill will recognize that the YKL-40 assay can be performed directly on the whole blood or the

whole blood can be fractionated. The term "whole blood" as used in claim 49 is generic to both possibilities. The use of the term reasonably apprises one of skill

re can be on the As recognized even by the Examiner in the phrasing of her rejection

35 U.S.C. §102.

Claims 1, 9-13, 15-17, 38, 39, 47-50, 52, 56-57, and 59-61 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Johansen *et al.* (1995) *Eur. J. Cancer*, 31A(9): 1437-1442. Claims 1, 4-10, 11-18, 47-49, and 56-62 were rejected under 102(e) as allegedly anticipated by Robbins *et al.* (U.S. Patent 5,726,061, filed on 10/08/1996). Applicants traverse by amendment and argument.

Johansen *et al.*

The Examiner is respectfully reminded that anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." *Kalman v Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983).

In the instant case, independent claims 1, 38, and 47, as amended herein each recite a list of cancers **that does not include breast cancer**. In contrast, Johansen *et al.* only makes reference to breast cancer and fails to identify any of the cancers recited in the pending independent claims. Accordingly, **all limitations** of the pending claims are not found in Johansen *et al.* Accordingly, Johansen *et al.* fails to anticipate claims 1, 9-13, 15-17, 38, 39, 47-50, 52, 56-57, and 59-61 and the rejection of these claims under 35 U.S.C. §102(b) on these grounds should be withdrawn.

Robbins *et al.*

Claims 1, 4-10, 11-18, 47-49, and 56-62 were rejected under 102(e) as allegedly anticipated by Robbins *et al.* (U.S. Patent 5,726,061, filed on 10/08/1996). Applicants respectfully traverse.

Claims 1, 4-10, and 11-18 are directed to "A method to screen for **recurrence** of a cancer after removal of a primary tumor" where the method involves "obtaining a biological sample comprising YKL-40 from a cancer patient **following removal of a primary tumor**. . . "

In contrast, Robbins *et al.* discloses "a method of screening for **early detection** of colorectal cancer in patients." [emphasis added] (col., 3, lines 12-13).

Because Robbins *et al.* is directed to "early detection" of cancer, **there is no teaching or disclosure of screening for recurrence of a cancer after removal of a primary tumor**. Consequently

Robbins *et al.* does not anticipate claims 1, 4-10, and 11-18 and the rejection of these claims under 35 U.S.C. §102(b) on these grounds should be withdrawn.

Independent claim 47 is amended herein to recite particular cancers. This list **does not** include colorectal cancer. Claim 47 and dependent claims 48-49, and 56-62 thus recite cancers that are not taught by Robbins *et al.* Robbins *et al.* thus fails to provide all the limitations of these claims and is therefore not anticipatory. Accordingly the rejection of claims 47-49 and 56-62 under 35 U.S.C. §102(b) in light of Robbins *et al.* should be withdrawn.

35 U.S.C. §103(a).

Claims 1-18, and 47-62 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of Johansen *et al. supra* in view of Maggio *et al.* (U.S. Patent 4,828,981) in light of Harlow *et al.* (1998) Antibodies, A laboratory manual, pages 148-212, or Price *et al.* (WO95/01995). The Examiner indicated that Johansen *et al.* allegedly teaches the use of YKL-40 as a marker for breast cancer. The Examiner acknowledged that Johansen *et al.* fails to disclose the types of cancer recited in the presently pending claims, a monoclonal antibody, and other sources of samples and relied on Price et al. as allegedly teaching the testing of serum and synovial fluid. The Examiner also relied on Harlow *et al.*, and Maggio *et al.* as teaching antibodies and competitive immunoassays, respectively. Applicants respectfully traverse.

A *prima facie* case of obviousness requires that the combination of the cited art, taken with general knowledge in the field, must provide all of the elements of the claimed invention. When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. *In re Geiger*, 815 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). Moreover, to support an obviousness rejection, the cited references must additionally provide a reasonable expectation of success. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991), *citing In re Dow Chemical Co.,* 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Applicants explain below that the cited art fails to provide a teaching of the use of YKL-40 as a prognostic marker for any cancer other than breast cancer. The cited art therefore fails to provide all the elements of the claimed invention and also fails to provide a reasonable expectation of success.

The cited art offers no teachings of cancers other than breast cancer.

The cited art fails to offer any teaching or suggestion of the use of YKL-40 as a **prognostic** for any cancer other than breast cancer. Johansen *et al.* is concerned solely with the use of YKL-40 as a prognostic marker in breast cancer:

> In the present study, we have assessed whether the level of serum YKL-40 reflects disease activity, localization of metastases and prognosis of survival in patients **with recurrent breast cancer**. [emphasis added] (page 1438, column 1).

Similarly, Price *et al.* (WO 95/01995) also only describes the use of YKL-40 as a prognostic for survival of a **breast cancer** patient. (*see, e.g.,* claim 14). Neither reference offers any teaching or suggestion whatsoever regarding the use of YKL-40 as a prognostic marker for any other cancer. Accordingly, these references fail to provide all the elements of the presently claimed invention.

This failure is not remedied by Harlow *et al.*, or Maggio *et al.*. As recognized by the Examiner, these references simply teach antibodies and competitive immunoassays, and make no mention whatsoever of YKL-40.

In view of this the cited art, in combination, fails to provide all the elements of the presently claimed invention. The Examiner has failed to make her *prima facie* case of obviousness and the rejection of claims 1-18, and 47-62 under 35 U.S.C. §103(a) should be withdrawn.

The cited art offers no reasonable expectation of success.

The cited art also fails to provide any reasonable expectation of success (*i.e.* that YKL-40 could function as a prognostic marker for any cancer other than breast cancer). Prior to the present application, the only disclosure of YKL-40 as a **prognostic** marker for cancer was with respect to breast cancer.

It was in the present application that the prognostic value of YKL-40 was identified for prostate cancer (*see, e.g.,* Example 8), colorectal cancer (*see, e.g.,* Example 7), small lung cell carcinoma (*see, e.g.,* Example 9). These data, taken with the prognostic data for breast cancer (*see, e.g.,* Example 6) lead one of skill in the art to conclude that YKL-40 is generally an effective marker for cancer prognosis.

Lacking the additional teaching regarding other cancer, however, one of skill in the art could not conclude from observations of a single type of cancer that YKL-40 would be an effective prognostic marker for any other type of cancer. Teachings based on observations of a single type of

cancer simply fail to provide any reasonable expectation of success that YKL-40 could function as a prognostic marker for any cancer other than breast cancer.

The Examiner's rejection is in effect improper hindsight reconstruction substituting the proper standard of obviousness with an "**obvious to try**" standard. The Examiner is respectfully reminded that the "obvious to try" standard has been repeatedly rejected by the Patent Office Board of Appeals and the Federal Circuit. Indeed, "most technological advance is the fruit of methodical, persistent investigation, as is recognized in 37 U.S.C §103 ('Patentability shall not be negatived by the manner in which the invention was made')." *See, In re Dow Chemical Company* 5 USPQ2d at 1531 (Fed. Cir., 1988).

In view of the foregoing, the cited art, lacking the teaching provided in the present specification fails to provide any reasonable expectation of success (*i.e.* that YKL-40 could function as a prognostic marker for any cancer other than breast cancer). Accordingly, the Examiner has failed to make her *prima facie* case and the rejection of claims 1-18, and 47-62 under 35 U.S.C. §103(a) should be withdrawn.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 337-7871.

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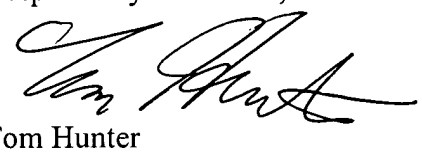
Respectfully submitted,



Tom Hunter
Reg. No: 38,498

Part/#28

APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN 09/164,862 WITH ENTRY OF THIS AMENDMENT

In the claims:

1. A method for estimating **[length of survival]**survival expectancy of a cancer patient, said method comprising:

(a) obtaining a biological sample **comprising YKL-40** from a cancer patient having at least a preliminary diagnosis of a cancer selected from the group consisting of a lung cancer, a bronchus cancer, a colorectal cancer, a prostate cancer, **[a breast cancer,]** a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma;

(b) measuring [a]**the** level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level **found in the same sample from a [in]** normal healthy human**[s]** wherein a sample YKL-40 level in excess of YKL-40 levels in **the same sample from a** normal healthy human**[s]** indicates a reduced survival expectancy compared to patients with normal YKL-40 level.

10. The method of claim 1, wherein said biological sample is a sample selected from the group consisting of whole blood, plasma, serum, synovial fluid, cerebrospinal fluid, bronchial lavage, ascites fluid, bone marrow aspirate, pleural effusion, urine, **[or]and** tumor tissue.

38. A method to screen for recurrence of a cancer after removal of a primary tumor, said method comprising:**[:]**

(a) obtaining a biological sample **comprising YKL-40** from a cancer patient following removal of a primary tumor **selected from the group consisting of a lung cancer, a bronchus cancer, a colorectal cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral**

nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma; and

(b) measuring a level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level **found in the same sample** in **a** normal healthy human**[s]** wherein a sample YKL-40 level in excess of YKL-40 levels in **a** normal healthy human**[s]** indicates a possible recurrence of said cancer.

47. A method of screening for a cancer, in a mammal, said method comprising:

(a) obtaining a biological sample **comprising YKL-40** from said mammal;

(b) measuring **[a]the** level of YKL-40 in said sample and comparing the level to the YKL-40 level found in **the same sample from [that of]** a normal healthy mammal, wherein a statistically significant difference in YKL-40 level**[s]in the sample being tested compared to the sample from a normal healthy mammal** indicates the presence of a cancer **selected from the group consisting of a lung cancer, a bronchus cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma**.

50. The method of claim 47, wherein said cancer is selected from the group consisting of a breast cancer, **[a colon cancer,]** a lung cancer, and a prostate cancer.

51. The method of claim 47, wherein said cancer is selected from the group consisting of a stomach cancer, a cervical cancer, an**[d]** ovarian cancer, and a malignant melanoma.

APPENDIX B

CLAIMS PENDING IN USSN 09/164,862 WITH ENTRY OF THIS AMENDMENT

1. A method for estimating survival expectancy of a cancer patient, said method comprising:

(a) obtaining a biological sample comprising YKL-40 from a cancer patient having at least a preliminary diagnosis of a cancer selected from the group consisting of a lung cancer, a bronchus cancer, a colorectal cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma;

(b) measuring the level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level found in the same sample from a normal healthy human wherein a sample YKL-40 level in excess of YKL-40 levels in the same sample from a normal healthy human indicates a reduced survival expectancy compared to patients with normal YKL-40 level.

2. The method of claim 1, wherein said patient has a diagnosis of prostate cancer.

3. The method of claim 1, wherein said patient has a diagnosis of lung cancer.

4. The method of claim 1, wherein said patient has a diagnosis of a colorectal cancer.

5. The method of claim 4, wherein said patient is diagnosed with a Duke's stage A colorectal cancer.

6. The method of claim 4, wherein said patient is diagnosed with a Duke's stage B colorectal cancer.

7. The method of claim 4, wherein said patient is diagnosed with a Duke's stage C colorectal cancer.

8. The method of claim 4, wherein said patient is diagnosed with a Duke's stage D colorectal cancer.

9. The method of claim 1, wherein said biological sample is a primary tumor or a tissue affected by the cancer.

10. The method of claim 1, wherein said biological sample is a sample selected from the group consisting of whole blood, plasma, serum, synovial fluid, cerebrospinal fluid, bronchial lavage, ascites fluid, bone marrow aspirate, pleural effusion, urine, and tumor tissue.

11. The method of claim 1, wherein the level of YKL-40 is measured by immunohistochemical staining of cells comprising said biological sample.

12. The method of claim 11, wherein said cells are tumor tissue cells.

13. The method of claim 1, wherein the level of YKL-40 is measured using an immunoassay.

14. The method of claim 13, wherein said immunoassay is a competitive immunoassay.

15. The method of claim 13, wherein said immunoassay is an ELISA.

16. The method of claim 13, wherein said immunoassay is a radioimmunoassay (RIA).

17. The method of claim 13, wherein said immunoassay uses a polyclonal anti-YKL-40 antibody.

18. The method of claim 13, wherein said immunoassay uses a monoclonal anti-YKL-40 antibody.

38. A method to screen for recurrence of a cancer after removal of a primary tumor, said method comprising:

(a) obtaining a biological sample comprising YKL-40 from a cancer patient following removal of a primary tumor selected from the group consisting of a lung cancer, a bronchus

cancer, a colorectal cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma; and

(b) measuring a level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level found in the same sample in a normal healthy human wherein a sample YKL-40 level in excess of YKL-40 levels in a normal healthy human indicates a possible recurrence of said cancer.

39. The method of claim 38, wherein said method is repeated at a multiplicity of instances after removal of said primary tumor.

47. A method of screening for a cancer, in a mammal, said method comprising:

(a) obtaining a biological sample comprising YKL-40 from said mammal;

(b) measuring the level of YKL-40 in said sample and comparing the level to the YKL-40 level found in the same sample from a normal healthy mammal, wherein a statistically significant difference in YKL-40 level in the sample being tested compared to the sample from a normal healthy mammal indicates the presence of a cancer selected from the group consisting of a lung cancer, a bronchus cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma.

49. The method of claim 47, wherein said biological sample is a sample of whole blood, plasma, serum, synovial fluid, cerebrospinal fluid, bronchial lavage, ascites fluid, bone marrow aspirate, pleural effusion, urine, or tumor tissue.

50. The method of claim 47, wherein said cancer is selected from the group consisting of a breast cancer, a lung cancer, and a prostate cancer.

51. The method of claim 47, wherein said cancer is selected from the group consisting of a stomach cancer, a cervical cancer, an ovarian cancer, and a malignant melanoma.

52. The method of claim 50, wherein said cancer is a breast cancer.

54. The method of claim 50, wherein said cancer is a prostate cancer.

55. The method of claim 50, wherein said cancer is a lung cancer.

56. The method of claim 47, wherein said mammal is a human.

57. The method of claim 47, wherein the level of YKL-40 is measured using an immunoassay.

58. The method of claim 57, wherein said immunoassay is a competitive immunoassay.

59. The method of claim 57, wherein said immunoassay is an ELISA.

60. The method of claim 57, wherein said immunoassay is a radioimmunoassay (RIA).

61. The method of claim 57, wherein said immunoassay uses a polyclonal anti-YKL-40 antibody.

62. The method of claim 57, wherein said immunoassay uses a monoclonal anti-YKL-40 antibody.